PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Blincyto Prior Authorization Policy
- Blincyto® (blinatumomab intravenous infusion – Amgen)

REVIEW DATE: 09/07/2022

OVERVIEW
Blincyto, a bispecific CD19-directed CD3 T-cell engager, is indicated for the treatment of adults and children for the following uses:[1]
- **Minimal residual disease (MRD)-positive, CD19-positive B-cell precursor acute lymphoblastic leukemia** (ALL) in first or second complete remission with MRD ≥ 0.1%.
- **Relapsed or refractory CD19-positive B-cell ALL**.

Guidelines
The National Comprehensive Cancer Network (NCCN) guidelines on **Acute Lymphoblastic Leukemia** (version 1.2022 – April 4, 2022) and **Pediatric Acute Lymphoblastic Leukemia** (version 1.2022 – October 1, 2021) recommend Blincyto for relapsed/refractory B-cell ALL; consolidation therapy in adolescents, young adults, and adults after complete response to induction therapy; and for pediatric patients with MRD positive disease or less than complete response.[2-4]

Safety
Blincyto contains a boxed warning for cytokine release syndrome which may be life-threatening or fatal and neurologic toxicities which may be severe, life-threatening or fatal.[1] Stop or discontinue Blincyto as recommended for either toxicity.

POLICY STATEMENT
Prior Authorization is recommended for prescription benefit coverage of Blincyto. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Blincyto, as well as the monitoring required for adverse events and long-term efficacy, approval requires Blincyto to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Blincyto is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Acute Lymphoblastic Leukemia.** Approve for 1 year if the patient meets the following criteria (A, B, and C):
   - **A)** Patient has B-cell precursor disease; AND
   - **B)** Patient meets one of the following (i, ii, or iii):
     - **i.** Patient is Philadelphia chromosome negative and meets one of the following (a, b, c, or d):
       - **a)** Patient has relapsed or refractory disease; OR

b) Patient is minimal residual disease positive; OR
c) The medication is used for consolidation therapy; OR
d) The medication is used for maintenance therapy; OR

ii. Patient is Philadelphia chromosome-like and minimal residual disease positive; OR
iii. Patient is Philadelphia chromosome positive and meets one of the following (a, b, c, or d):
a) Patient has tried at least one tyrosine kinase inhibitor (TKI) used for the treatment of acute lymphoblastic leukemia; OR
Note: Examples of a TKI include imatinib tablets, Sprycel (dasatinib tablets), Tasigna (nilotinib capsules).
b) Patient does not have a complete response to induction therapy; OR
c) Patient is minimal residual disease positive; OR
d) The medication is used for consolidation therapy; AND

C) Blincyto is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Blincyto is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Blincyto® intravenous infusion [prescribing information]. Thousand Oaks, CA: Amgen; February 2022.
2. The NCCN Pediatric Acute Lymphoblastic Leukemia Oncology Guidelines (version 1.2022 – October 1, 2021). © 2021 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 30, 2022.
3. The NCCN Acute Lymphoblastic Leukemia Clinical Practice Guidelines in Oncology (version 1.2022 – April 4, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 30, 2022.
4. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 30, 2022. Search term: blinatumomab.